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Scancell Holdings plc
("Scancell" or the "Company")

Scancell signs strategic partnership with PharmaJet for use of the Stratis® IM Needle-free delivery System in the development of SCIB1/iSCIB1+ cancer vaccine for Advanced Melanoma

Scancell Holdings plc (AIM: SCLP), the developer of novel immunotherapies for the treatment of cancer, today announces that it has signed a strategic partnership with PharmaJet for supply of the Stratis® Intramuscular (IM) Needle-free Injection System for delivery of Scancell's Immunobody® SCIB1/iSCIB1+ DNA vaccine for both clinical development and commercial use.

Delivering SCIB1/iSCIB1+ intramuscularly via Stratis® has shown effective uptake of the DNA vaccine and has the potential to provide clinical benefit to patients with advanced/metastatic melanoma by allowing native cellular machinery to express the target antigen and induce a potent anti-tumour response. To date, 60 patients across 15 clinical sites have successfully received a total of 171 doses of SCIB1/iSCIB1+ via Stratis®.

Stratis® has U.S. FDA 510(k) marketing clearance, CE Mark, and World Health Organization Prequalification to deliver medications and vaccines either intramuscularly or subcutaneously and has been widely accepted and favoured by patients and clinicians throughout the SCOPE Study.

The license agreement has been completed in preparation for the Phase 2/3 adaptive registrational trial planned for 2025, building on the previously announced exceptional data from the first 13 patients receiving SCIB1 in the ongoing SCOPE trial. Clinical data is expected from SCIB1 and iSCIB1+ in Q4 2024 and Q1 2025, respectively. The delivery of SCIB1/ iSCIB1+ vaccine with Stratis® offers patients speed of treatment as an off the shelf therapeutic cancer vaccine with the convenience of needle-free delivery that enhances the patient experience.

Prof Lindy Durrant, Chief Executive Officer, Scancell, commented: "Securing long term supply for the PharmaJet Stratis® Intramuscular Needle-free Injection System is an important step in allowing the clinical and commercial development of SCIB1/iSCIB1+. We are pleased that PharmaJet's delivery system works effectively with our SCIB1/iSCIB1+ therapeutic cancer vaccines and offers a well-received immunisation for patients. Our ultimate goal for Scancell is to deliver an off the shelf, safe, tolerable, effective therapy that can provide potent and durable anti-tumour responses for unresectable stage IV melanoma which currently has a 5-year survival of 35%, according to the SEER database, and we believe this agreement will bring us another step closer to achieving this goal."

Dr Heather Shaw, Consultant Medical Oncologist, Mount Vernon Cancer Centre and the UCLH, commented: "The convenience of an off-the-shelf vaccine for patients, clinicians and the healthcare system is further optimised with the ease of delivery of SCIB1/iSCIB1+ with the Stratis® Needle-free Injection System. Our patients on the SCOPE study are very comfortable with the delivery system and our research team benefit from the convenience of delivering the SCIB1/iSCIB1+ via Stratis®."

Nathalie Landry, Chief Scientific Officer at PharmaJet, commented: "We are excited to partner with Scancell to develop and commercialise their SCIB1/iSCIB1+ DNA vaccine for advanced melanoma. This partnership aligns with PharmaJet's strategy to enable improved delivery of nucleic acid-based vaccines and therapies for oncology."

-ENDS-

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About SCIB1/iSCIB1+
SCIB1 is the lead product from the Company's ImmunoBody® DNA Vaccine platform, which uses the body's immune system to identify, attack and destroy tumours. iSCIB1+ is a modified version of SCIB1 developed using Scancell's AvidiMab® platform to enhance its potency compared to SCIB1. iSCIB1+ also includes additional melanoma-specific epitopes so it has the potential to be effective in a broader patient population beyond the 40% of patients with the tissue type treatable with SCIB1, where treatment is human leukocyte antigen (HLA) dependent.

About the SCOPE Study
The SCOPE Study (NCT04079166) is a Phase 2, Multicentre, Open-Label, Umbrella Study of SCIB1 and iSCIB1+ in Patients With Advanced Unresectable Melanoma Receiving Nivolumab With Ipilimumab or SCIB1 With Pembrolizumab to determine the response rate and safety and tolerability of intramuscular SCIB1 or iSCIB1+ when added to nivolumab (Opdivo) with ipilimumab (Yervoy) or SCIB1 with pembrolizumab (Keytruda). Conducted across approximately 15 sites in the United Kingdom, this multi-site trial aims to demonstrate durable and potent anti-tumour activity and ORR of SCIB1/Iscib1+ in addition to standard of care checkpoint inhibitors. Additional endpoints include duration of response (DOR), progression free survival (PFS), overall survival (OS), safety, and tolerability. Participants receive up to 10 doses of either SCIB1 or iSCIB1+ using PharmaJet Stratis® Intramuscular Needle-free Injection System in the upper arm or upper leg, up to 85 weeks, in combination with nivolumab with ipilimumab or SCIB1 with pembrolizumab. More information on this trial can be found at clinicaltrials.gov or www.clinicaltrialsregister.eu.

About Scancell
Scancell is a clinical stage biopharmaceutical company that is leveraging its proprietary research, built up over many years of studying the human adaptive immune system, to generate novel medicines to treat significant unmet needs in cancer. The Company is building a pipeline of innovative products by utilising its four technology platforms: Moditope® and ImmunoBody® for vaccines and GlyMab® and AvidiMab® for antibodies.

Adaptive immune responses include antibodies and T cells (CD4 and CD8), both of which can recognise damaged or infected cells. In order to destroy such cancerous or infected cells, Scancell uses either vaccines to induce immune responses or monoclonal antibodies (mAbs) to redirect immune cells or drugs. The Company's approaches are that vaccines (ImmunoBody® and Moditope®) use unique receptors to target antigens to activated antigen presenting cells whereas its mAb portfolio targets glycans or sugars that are added onto proteins and / or lipids (GlyMab®) or enhances the potency of antibodies and their ability to directly kill tumour cells (AvidiMab®).

For further information about Scancell, please visit: https://www.scancell.co.uk/

About PharmaJet
The PharmaJet mission is to improve the performance and outcomes of injectables with our enabling technology that better activates the immune system. We are committed to helping our partners realize their research and commercialization goals while making an impact on public health. PharmaJet Precision Delivery Systems™ can improve increased vaccine effectiveness, allow for a preferred patient and caregiver experience, and offer a proven path to commercialization. They are also safe, fast, and easy-to-use. The Stratis® System has U.S. FDA 510(k) marketing clearance, CE Mark, and WHO PQS certification to deliver medications and vaccines either intramuscularly or subcutaneously. The Tropis System has CE Mark and WHO PQS certification for intradermal injections. They are both commercially available for global immunization programs. For more information or if you are interested in partnering with PharmaJet to improve the impact of your novel development program, visit https://pharmajet.com or contact PharmaJet here. Follow us on LinkedIn.